AFFIDAVIT FOR SERVICE OF PROCESS ON THE SECRETARY OF THE COMMONWEALTH

Commonwealth of Virginia

Case No. CL13-15366

FAIRFAX COUNTY Circuit Court

Deirdre Williamson Jain, and Emily Ruth Williamson, Individually, and as Co-Administrators of the Estate of Joseph Seth Williamson, II, Deceased	v.	Abbott Laboratories Inc., et al. CT Corporation System, RA, 208 S. LaSalle St., Ste. 814 Chicago, IL 60604

TO THE PERSON PREPARING THIS AFFIDAVIT: You must comply with the appropriate requirements listed on the back of this form.

Attachments: ☒ Summons and Complaint ☐ Notice ☐ .....

I, the undersigned Affiant, state under oath that

☒ the above-named defendant ☐ .....

whose last known address is ☒ same as above ☐ .....

1. ☒ is a non-resident of the Commonwealth of Virginia or a foreign corporation and Virginia Code § 8.01-328.1(A) applies (see NON-RESIDENCE GROUNDS REQUIREMENT on reverse).
2. ☐ is a person whom the party seeking service, after exercising due diligence, has been unable to locate (see DUE DILIGENCE REQUIREMENT ON BACK)

☐ is the hearing date and time on the attached process or notice.

10/15/13
DATE

☐ PARTY ☑ PARTY'S ATTORNEY ☐ PARTY'S AGENT ☐ PARTY'S REGULAR AND *BONA FIDE* EMPLOYEE

State of Virginia ☐ City ☑ County of Fairfax

Acknowledged, subscribed and sworn to before me this day by Mark Donna Ricci
PRINT NAME OF SIGNATORY

10/15/13
DATE

Marie Donna Ricci

☐ CLERK ☐ MAGISTRATE ☑ NOTARY PUBLIC

Notary Registration No. 7375576 My commission expires 12/31/2014

MARIE DONNA RICCI NOTARY PUBLIC REG.# 7375576 COMMISSION EXPIRES 12/31/2014 COMMONWEALTH OF VIRGINIA

☒ Verification of the date of filing of the certificate of compliance is requested and a self-addressed stamped envelope is provided.

NOTICE TO THE RECIPIENT from the Office of the Secretary of the Commonwealth of Virginia:

You are being served with this notice and attached pleadings under Section 8.01-329 of the Code of Virginia which designates the Secretary of the Commonwealth as statutory agent for Service of Process. The Secretary of the Commonwealth's ONLY responsibility is to mail, by certified mail, return receipt requested, the enclosed papers to you. If you have any questions concerning these documents, you may wish to seek advice from a lawyer.

SERVICE OF PROCESS IS EFFECTIVE ON THE DATE THAT THE CERTIFICATE OF COMPLIANCE IS FILED WITH THE ABOVE-NAMED COURT.

CERTIFICATE OF COMPLIANCE

I, the undersigned, Clerk in the Office of the Secretary of the Commonwealth, hereby certify the following:

1. On OCT 29 2013, legal service in the above-styled case was made upon the Secretary of the Commonwealth, as statutory agent for persons to be served in accordance with Section 8.01-329 of the Code of Virginia, as amended.
2. On OCT 30 2013, papers described in the Affidavit were forwarded by certified mail, return receipt requested, to the party designated to be served with process in the Affidavit.

SERVICE OF PROCESS CLERK, DESIGNATED BY THE AUTHORITY OF THE SECRETARY OF THE COMMONWEALTH

FORM CC-1418 (MASTER, PAGE ONE OF TWO) 11/07
VA. CODE §§ 8.01-301, -310, -329; 55-218.1; 57-51

EXHIBIT A

AFFIDAVIT FOR SERVICE OF PROCESS ON THE SECRETARY OF THE COMMONWEALTH
Commonwealth of Virginia

Case No. CL13-15366

FAIRFAX COUNTY Circuit Court

Deirdre Williamson Jain, and Emily Ruth Williamson, Individually, and as Co-Administrators of the Estate of Joseph Seth Williamson, II, Deceased

v.

Hospira, Inc., et al.
CT Corporation System, RA, 208 S. LaSalle St., Ste. 814
Chicago, IL 60604

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[ ] is the hearing date and time on the attached process or notice.

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DATE

☐ PARTY ☒ PARTY'S ATTORNEY ☐ PARTY'S AGENT ☐ PARTY'S REGULAR AND *BONA FIDE* EMPLOYEE

State of Virginia ☐ City ☒ County of Fairfax

Acknowledged, subscribed and sworn to before me this day by Marie Donna Ricci
PRINT NAME OF SIGNATORY

Oct. 15, 2013
DATE

Marie Donna Ricci
☐ CLERK ☐ MAGISTRATE ☒ ☐ NOTARY PUBLIC

Notary Registration No. 7375576 My commission expires: 12/31/2014

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FORM CC-1418 (MASTER, PAGE ONE OF TWO) 11/07
VA. CODE §§ 8.01-301, -310, -329; 55-218.1; 57-51

CIRCUIT COURT FOR FAIRFAX COUNTY, VIRGINIA

Deirdre Williamson Jain, et al.	
Plaintiff(s)	**Case No.: CL-2013-0015366**
v.	
Abbot Laboratories Inc., et al.	
Defendant(s)	

AFFIDAVIT OF SERVICE

I, Kenneth V. Condrey, a Private Process Server, being duly sworn, depose and say:

That I have been duly authorized to make service of the Summons and Complaint with Exhibit 1 in the above entitled case.

That I am over the age of eighteen years and I am not a party to or otherwise interested in this matter.

That on October 17, 2013 at 3:00 PM, I served Abbott Laboratories d/b/a Abbott Laboratories Inc. c/o CT Corporation System, Registered Agent with the Summons and Complaint with Exhibit 1 at 4701 Cox Road, Suite 301, Glen Allen, Virginia 23060 by serving Teresa Brown, Designated Agent, authorized to accept.

Teresa Brown is described herein:
Gender: Female Race/Skin: Black Hair: Black Age: 30 Height: 5'2" Weight: 200

I do solemnly declare and affirm under penalty of perjury that the information set forth herein is correct to the best of my knowledge, information and belief.

Kenneth V. Condrey
CAPITOL PROCESS SERVICES, INC.
1827 18th Street, NW
Washington, DC 20009-5526
(202) 667-0050

Subscribed and sworn to before me, a notary public, on this 18TH day of October, 2013.

Notary Public

My Commission Expires: 10/31/13

KAREN L. RICE
NOTARY PUBLIC - VIRGINIA
CHESTERFIELD COUNTY
MY COMMISSION EXPIRES: 10/31/13
REGISTRATION #355099

ID: 13-098337

Client Reference: N/A

Service Authorization

CT Corporation System is registered agent for various corporations, limited liability companies and partnerships. The following persons are designated in the office of the corporation upon whom any process, notice or demand may be served as representatives of the Corporation.

Tinika C. Baylor

Katie E. Bush

Teresa Brown

Dacia Jamison

Lisa Uttech

This authorization pertains to the authority of individuals to receive process on behalf of CT Corporation System, Business Filings Incorporated, and National Registered Agents, Inc. It does not certify the receipt or acceptance of any specific process.

Lisa Uttech
Corporate Operations Manager
CT Corporation System
A Wolters Kluwer Company

State of Virginia
County of Henrico

This day personally appeared before me, Lisa Uttech, whose name is signed above and who, being first duly sworn, upon her oath, states that the foregoing Affidavit is true to the best of her knowledge and belief.

Subscribed and sworn before me this 17 day of April, 2012

#286304

Notary Public

8/31/12

Complaint to Secretary of Commonwealth - Issued 10/23/13 - CW

Hall & Sethi, PLC
ATTORNEYS AT LAW

Robert T. Hall
Gobind S. Sethi
Holly Parkhurst Essing, Of Counsel
Samantha K. Sledd

October 15, 2013

FILED
CIVIL INTAKE
2013 OCT 18 PM 1:58
JOHN T. FREY
CLERK, CIRCUIT COURT
FAIRFAX, VA

John T. Frey, Clerk
Circuit Court of Fairfax County
4110 Chain Bridge Road
Fairfax, Virginia 22030

Re: ***Jain, et al. v. Abbott Laboratories Inc., et al.*; CL13-15366**

Dear Mr. Frey:

Enclosed please find **two sets** of the following documents for service of process on both Defendants **Abbott Laboratories Inc.** and **Hospira, Inc.** through the Secretary of the Commonwealth pursuant to Virginia Code §§ 8.01-301 and 8.01-329:

One copy of the Complaint to be served.

The original and four (4) copies of the Affidavit of Last Known Address for each Defendant.

One certified mail card addressed to each Defendant and returnable to our office.

One envelope addressed to each Defendant.

One self-addressed stamped envelope for return of service to party requesting service, our office.

A check payable to the Secretary of the Commonwealth in the amount of $28.00 which represents the required fee.

Please date-stamp and return a copy of the Affidavit for each Defendant to our office in the enclosed small envelope.

If you have any questions, please do not hesitate to contact me. Thank you for your assistance in this regard.

Very truly yours,

Samantha K. Sledd

12120 Sunset Hills Road, Suite 150 • Reston, Virginia 20190
Tel: 703.925.9500 • Fax: 703.925.9166
www.hallandsethi.com

AFFIDAVIT FOR SERVICE OF PROCESS ON THE SECRETARY OF THE COMMONWEALTH
Commonwealth of Virginia

Case No. CL13-15366

FAIRFAX COUNTY Circuit Court

Deirdre Williamson Jain, and Emily Ruth Williamson, Individually, and as Co-Administrators of the Estate of Joseph Seth Williamson, II, Deceased	v.	Abbott Laboratories Inc., et al. CT Corporation System, RA, 208 S. LaSalle St., Ste. 814 Chicago, IL 60604

TO THE PERSON PREPARING THIS AFFIDAVIT: You must comply with the appropriate requirements listed on the back of this form.

Attachments: ☒ Summons and Complaint ☐ Notice ☐ .....

FILED
2013 OCT 18 PM 1:58
CLERK CIRCUIT COURT
FAIRFAX, VA

I, the undersigned Affiant, state under oath that
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whose last known address is ☒ same as above ☐ .....

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[ ] is the hearing date and time on the attached process or notice.

10/15/13
DATE

☐ PARTY ☒ PARTY'S ATTORNEY ☐ PARTY'S AGENT ☐ PARTY'S REGULAR AND *BONA FIDE* EMPLOYEE

State of Virginia ☐ City ☑ County of Fairfax

Acknowledged, subscribed and sworn to before me this day by Mark Donna Ricci
PRINT NAME OF SIGNATORY

10/15/13
DATE

Marie Donna Ricci
☐ CLERK ☐ MAGISTRATE ☒ NOTARY PUBLIC

Notary Registration No. 7375576 My commission expires: 12/31/2014

MARIE DONNA RICCI NOTARY PUBLIC REG. # 7375576 COMMISSION EXPIRES 12/31/2014 COMMONWEALTH OF VIRGINIA

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FORM CC-1418 (MASTER, PAGE ONE OF TWO) 11/07
VA. CODE §§ 8.01-301, -310, -329; 55-218.1; 57-51

AFFIDAVIT FOR SERVICE OF PROCESS ON THE SECRETARY OF THE COMMONWEALTH

Commonwealth of Virginia

Case No. CL13-15366

FAIRFAX COUNTY Circuit Court

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Hospira, Inc., et al.
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Chicago, IL 60604

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FILED
2013 OCT 18 PM 1:59
CLERK CIRCUIT COURT
FAIRFAX, VIRGINIA

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10/15/13
DATE

☐ PARTY ☒ PARTY'S ATTORNEY ☐ PARTY'S AGENT ☐ PARTY'S REGULAR AND *BONA FIDE* EMPLOYEE

State of Virginia ☐ City ☒ County of Fairfax

Acknowledged, subscribed and sworn to before me this day by Marie Donna Ricci
PRINT NAME OF SIGNATORY

Oct. 15, 2013
DATE

Marie Donna Ricci
☐ CLERK ☐ MAGISTRATE ☒ NOTARY PUBLIC

Notary Registration No. 7375576 My commission expires: 12/31/2014

MARIE DONNA RICCI NOTARY PUBLIC REG # 7375576 COMMISSION EXPIRES 12/31/2014 COMMONWEALTH OF VIRGINIA

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SERVICE OF PROCESS CLERK, DESIGNATED
BY THE AUTHORITY OF THE SECRETARY OF THE COMMONWEALTH

FAIRFAX CIRCUIT COURT
CIVIL CASE COVERSHEET

Parties:

Plaintiffs	Defendants
1. Deirdre Williamson Jain and	1. Abbott Laboratories, Inc.
2. Emily Ruth Williamson, co - administrators of the	2. Abbott Laboratories
3. Estate of Joseph Seth Williamson, II	3. Hospira, Inc.

2013-15366

***Plaintiff proceeding without Counsel – Address and Daytime Phone Number required on Complaint**

Plaintiff Attorney:

Name: Robert T. Hall Bar ID: 4826

Firm: Hall & Sethi, PLC

Street: 12120 Sunset Hills Rd., Ste. 150

City: Reston State: VA Zip: 20190

Phone Number: 703-925-9500 Fax Number: 703-925-9166

E-mail Address: rthall@hallandsethi.com

FILED
CIVIL INTAKE
2013 OCT -4 PM 12:42
JOHN T. FREY
CLERK, CIRCUIT COURT
FAIRFAX, VA

Nature of Complaint (Check only one) *** Cases in the Civil Tracking Program**

☐ Administrative Appeal	☐ Defamation *	☐ Malpractice – Medical *
☐ Affirmation of Marriage	☐ Delinquent Taxes *	☐ Mechanics/Vendors Lien *
☐ Aid & Guidance	☐ Eminent Domain	☐ Partition *
☐ Appeal Decision of Board of Zoning	☐ Encumber/Sell Real Estate	☐ Personal Injury – Assault *
☐ Appeal of Process/Judicial Appeal	☐ Erroneous Assessments	☐ Personal Injury – Auto *
☐ Appointment Church/Organization Trustees	☐ Expungement	☐ Personal Injury – Emotional *
☐ Arbitration	☐ False Arrest/Imprisonment*	☐ Personal Injury – Premises Liability*
☐ Attachment	☐ Fiduciary/Estate Complaint	☐ Property Damage*
☐ Complaint – Equity *	☐ Garnishment–Federal–180 days	☑ Products Liability*
☐ Complaint – Legal Cause of Action *	☐ Garnishment–Wage–180 days	☐ Quiet Title *
☐ Compromise Settlement	☐ Garnishment–Other – 90 days	☐ Real Estate *
☐ Condemnation*	☐ Guardian/Conservator Adult	☐ Restoration of Driving Privilege
☐ Confession of Judgment	☐ Guardianship/Minor	☐ Vital Record Correction
☐ Construction *	☐ Injunction	☐ Writ Habeas Corpus
☐ Contract *	☐ Interpleader	☐ Writ Mandamus
☐ Conversion*	☐ Insurance *	☐ Wrongful Death*
☐ Court Satisfaction of Judgment	☐ Judicial Review	☐ Wrongful Discharge *
☐ Declare Death	☐ Malicious Prosecution *	☐ OTHER:
☐ Declaratory Judgment *	☐ Malpractice – Legal *	

Damages in the amount of $ 10000000.00 **are claimed.**

Requested Service: ☐ Sheriff ☑ Private Process Server ☐ DMV ☐ Secretary of Commonwealth ☐ State Corporation Commission ☐ Publication ☐ No Service at this time

VIRGINIA:

IN THE CIRCUIT COURT OF FAIRFAX COUNTY

DEIRDRE WILLIAMSON JAIN, and
EMILY RUTH WILLIAMSON, Individually,
and as Co-Administrators of the Estate of
Joseph Seth Williamson, II, Deceased

Plaintiffs,

v.

ABBOTT LABORATORIES INC.
(A Delaware Corporation)
100 Abbott Park Road
Abbott Park, Illinois 60064

SERVE: Secretary of the Commonwealth
1111 East Broad Street, 4th Floor
Richmond, Virginia 23219

and

ABBOTT LABORATORIES
(An Illinois Corporation, authorized to do business in Virginia as ABBOTT LABORATORIES INC.)
100 Abbott Park Road
Abbott Park, Illinois 60064

SERVE: CT Corporation System, RA
4701 Cox Road, Suite 301
Glen Allen, Virginia 23060

and

HOSPIRA, INC.
(A Delaware Corporation)
275 North Field Drive
Lake Forest, Illinois 60045

SERVE: Secretary of the Commonwealth
1111 East Broad Street, 4th Floor
Richmond, Virginia 23219

Defendants.

Case No. 2013-15366

COMPLAINT

COME NOW Plaintiffs, Deirdre Williamson Jain and Emily Ruth Williamson, Individually, and as Co-Administrators of the Estate of Joseph Seth Williamson, II, Deceased, by counsel, and file this action for wrongful death pursuant to §8.01-50 *et seq.* of the Virginia Code, and for their Complaint, state and aver as follows:

1. On October 13, 2011, in Montgomery County, Virginia, Plaintiffs Deirdre Williamson Jain and Emily Ruth Williamson qualified as Co-Administrators of the Estate of Joseph Seth Williamson, II and as such, are duly authorized personal representatives able to bring a claim for his wrongful death. See *Exhibit 1* attached and incorporated by reference.

2. Plaintiffs Deirdre Williamson Jain and Emily Ruth Williamson are the sole statutory beneficiaries of Joseph Seth Williamson, II under Va. Code § 8.01-53.

3. Venue is proper pursuant to Virginia Code § 8.01-262(10) in that Plaintiff Deirdre Williamson Jain is a resident of Fairfax County and all Defendants are nonresidents of the Commonwealth of Virginia.

4. On October 7, 2011, Joseph Seth Williamson, II died in a Virginia hospital as a result of receiving an overdose of the drug Dilaudid, which had been prescribed for him for the management of pain following hernia repair surgery.

5. The Dilaudid prescribed for him by his surgeon was in a dosage appropriate to his level of pain.

6. The Dilaudid administered to him in the hospital was administered via a Hospira LifeCare PCA® Infusion System with Hospira MedNet™ Software.

7. Because of defects in the design and manufacture of this Patient Controlled Analgesia ("PCA") infusion pump, its System Operating Manual and its supporting software,

Plaintiffs' Decedent was administered Dilaudid dosages five times the strength prescribed by his surgeon.

8. As a direct and proximate result of the defects in the design and manufacture of the PCA infusion pump used to administer Decedent's Dilaudid, Decedent suffered respiratory compromise, respiratory depression and ultimately, cardio-respiratory arrest and death.

9. At all times relevant to this proceeding, Defendant Abbott Laboratories, also known as Abbott Laboratories, Inc. (hereinafter collectively referred to as "Abbott"), designed, fabricated and manufactured a series of medical infusion pumps intended to deliver medication in controlled doses to hospital patients and others. The design, fabrication and manufacture of infusion pumps by Defendant Abbott were initially conducted in what was then known as its Hospira Products Division.

10. Defendant Abbott's infusion pump product line included so-called PCA infusion pumps which were intended to permit a physician to prescribe and a nurse to administer, via the pump, doses of pain medication in accordance with the physician's prescription for the administration of the pain medication, and to permit the patient to augment or supplement the medication by "requesting" additional pre-programmed dosages of the pain medication provided by activating a patient pendant.

11. Each activation of the patient pendant would provide the patient with the fixed additional quantity or "bolus" of the medication as prescribed by the physician, subject to restrictions likewise pre-programmed into the infusion pump by the nursing staff.

12. The restrictions on patient-requested supplemental boluses of the medication included timed lockouts between doses so that the patient could not obtain more than a single bolus of a prescribed dose within a given time interval. For example, a patient might be limited

to the delivery of 0.2 milligrams of the prescribed medication with 20 minute lockouts, i.e. the patient could not augment his medication by more than 0.2 milligrams every 20 minutes. Any attempt to obtain more than 0.2 milligrams every 20 minutes would be "locked out," or prevented, and a history of the request and refusal would be logged in an electronic database in the pump software.

13. Additionally, the PCA pump software permitted the doctor to prescribe and the nurse to program the pump to administer an ongoing dose over time and set a maximum dosage over a longer period, such that, for example, the patient could not be administered more than 3 milligrams of the medication every four hours.

14. On September 16, 2003, Defendant Abbott incorporated its Hospira Products Division as a stock corporation named Hospira, Inc. under the laws of the State of Delaware.

15. On April 12, 2004, Defendant Abbott spun off its shares of Hospira, Inc. to the shareholders of Defendant Abbott.

16. On September 14, 2004, Defendant Hospira, Inc. ("Hospira") notified the United States Food and Drug Administration ("FDA") of its intent to market what was to be called its LifeCare PCA® Infusion System with Hospira MedNet™ Software. It sought to qualify this pump and its software under Section 510(k) of the Federal Food, Drug and Cosmetic Act ("the Act") as being substantially similar to two devices previously marketed: the Abbott LifeCare® PCA 3 Infuser and the Hospira Plum A+® Infusion System with Hospira MedNet™ Software.

17. On October 8, 2004, the FDA approved the marketing of the LifeCare PCA® Infusion System with Hospira MedNet™ Software on the grounds that it was substantially similar to products already being marketed. The marketing of this system did not require any further premarket approval application.

18. The Abbott LifeCare® PCA 3 Infuser, the predicate device upon which the Hospira LifeCare PCA® Infusion System with Hospira MedNet™ Software had been approved as "substantially similar," had itself received the FDA's approval under Section 510(k) of the Act upon the following representation and warranty: "When the practitioner places a vial into the pump, the bar code reader electronically scans the vial for recognition of the drug and the drug concentration. If recognition is achieved then programming will proceed. If the vial is not recognized then the pump will stop and not allow any further programming." *Abbott LifeCare® PCA 3 Infuser 510(k) Summary*, Abbott Laboratories, July 2, 2002. (emphasis added).

19. When Defendant Hospira sought approval under Section 510(k) of the Act for its LifeCare PCA® Infusion System with Hospira MedNet™ Software on the grounds that it was "substantially equivalent" to the Abbott LifeCare® PCA 3 Infuser, Hospira expressly represented and warranted to the FDA, and accordingly, to its hospital purchasers or lessees, that the product had been designed and manufactured so that it included "a bar code reader that recognizes Hospira- or Abbott-manufactured drug vials as well as hospital pharmacy-generated bar codes." *LifeCare PCA® Infusion System with Hospira MedNet™ Software 510(k) Summary*, Hospira, Inc., Sept. 14, 2004.

20. In so stating, Defendant Hospira impliedly represented to the FDA that as a substantially equivalent device to the Abbott LifeCare® PCA 3 Infuser, the Hospira LifeCare PCA® Infusion System with Hospira MedNet™ Software also allowed that: "When the practitioner places a vial into the pump, the bar code reader electronically scans the vial for recognition of the drug and the drug concentration. If recognition is achieved then programming will proceed. If the vial is not recognized then the pump will stop and not allow any further

programming." *Abbott LifeCare® PCA 3 Infuser 510(k) Summary*, Abbott Laboratories, July 2, 2002. (emphasis added).

21. However, that representation was not true, accurate or correct with respect to the Hospira LifeCare PCA® Infusion System with Hospira MedNet™ Software.

22. Such a representation was only accurate when an Abbott- or Hospira-manufactured drug vial or compatible hospital pharmacy-generated barcoded vial was placed in the pump.

23. There was one circumstance under which the representation and warranty could not be accurate, a condition not disclosed to the FDA. Practitioners would be permitted to insert into the subject pump a non-Abbott, non-Hospira, non-hospital pharmacy barcoded vial into the pump. This vial could not be read by the pump's barcode reader and as such, could not create software confirmation of the drug and its concentration, nor allow for lockout or shutdown of the remaining programming features of the pump.

24. In short, Hospira failed to reveal to the FDA that the safety feature introduced into the Abbott LifeCare® PCA 3 Infuser—that the pump could not be programmed for patient infusion until the pump first identified the drug and its concentration via the bar code reader—could be disabled or overridden in its new PCA pump.

25. Upon information and belief, the decision by Defendants to develop and offer the new LifeCare PCA® Infusion System with Hospira MedNet™ Software for sale or lease, with safety features which could be disabled or overridden, was market driven. Sales of the Abbott LifeCare® PCA 3 Infuser had been limited because neither Abbott nor Hospira offered the entire variety of drugs with its proprietary bar code that were being requested by physicians and hospitals for use in PCA pumps.

26. Notwithstanding the new pump's significant potential for the introduction of human error, Hospira further represented to the FDA, and accordingly, to the hospital purchasers or lessees of its pump, that "[t]he LifeCare PCA® Infusion System with Hospira MedNet™ Software is indicated for accurate, volumetric, infusion of analgesic drugs by continuous or patient-demanded (PCA) intravenous administration." *LifeCare PCA® Infusion System with Hospira MedNet™ Software 510(k) Summary*, Hospira, Inc., Sept. 14, 2004. (emphasis added).

27. Despite that representation, Hospira designed and manufactured a bypass for its safety system, a "further programming lockout." Instead of requiring the barcode reader to identify the drug and its concentration before permitting further programming, this lockout permitted the pump to be programmed by the nursing staff by manually entering the concentration of the drug, thereby bypassing the safety feature and creating an independently dangerous condition.

28. Were a nurse to manually program the pump, the data entry screen on the pump in which the concentration of the drug could be entered contained no instructions or warnings about *which* concentration should be entered.

29. The pump failed to specify whether staff should enter the concentration of the drug the physician had ordered or the concentration of the drug identified on the vial in the pump.

30. To the average, reasonably prudent nurse, the concentration to be entered was that stated in the physician's order. If the physician ordered that the patient was to receive 0.2 milligrams of the drug, then a reasonably prudent nurse would deem that the concentration to be entered.

31. However, the proper concentration to be programmed into the pump was in fact the concentration identified on the vial in the pump.

32. Unfortunately for Decedent, his nursing staff manually entered the concentration prescribed in his physician's order, 0.2 mg, not the concentration on the vial in the pump, 1 mg. As a result, Decedent was infused with five times the physician's prescribed concentration upon every cycling of the pump, with life ending consequences.

33. Every time Decedent was to receive 0.2 mg of Dilaudid, the PCA pump infused 1 mg of Dilaudid. Between the commencement of the PCA pump infusion and Decedent's demise, the patient received 12.5 milligrams of Dilaudid instead of receiving a total of 2.5 milligrams over a four-hour period.

34. As a proximate result of Defendants' conduct, as set out in this Complaint, Plaintiffs, the statutory beneficiaries of the Estate of Joseph Seth Williamson, II, have been damaged as more fully set out hereinafter.

COUNT I - NEGLIGENCE

35. Plaintiffs incorporate herein the allegations set forth in Paragraphs 1-34 as though set forth in full text.

36. Defendants had a duty to exercise reasonable care in the design, manufacture and distribution of the subject device.

37. Defendants breached this duty and acted negligently in the following ways:

a. The System Operating Manual for the subject pump produced and printed by Hospira, negligently failed to provide instructions for the programming of the drug concentration in the event that the drug concentration was to be entered manually, as in this case.

b. The System Operating Manual mistakenly and misleadingly encouraged the nursing staff to enter the concentration in the physician's prescription or order, not the concentration in the vial.

c. The System Operating Manual for the subject pump failed to warn the user of the known risks and hazards of the improper programming of the drug concentration.

d. The display on the subject pump failed to provide adequate instructions for the programming of the pump in the event that the drug concentration was entered manually.

e. The display on the pump failed to warn the user of the known risks and hazards of the improper programming of the drug concentration, including a warning that there was a specific risk that the pump could be easily misprogrammed by entry of a wrong drug concentration

f. Defendants were well aware as early as 2002 that misprogramming of the pump by nursing staff was a principal cause of medication errors in a hospital setting, yet had undertaken no human factor or engineering analyses to determine how and why these errors were occurring.

g. Defendants were specifically aware as early as 2008, and perhaps earlier, of the hazards posed when the drug concentration was entered manually by nursing staff.

h. Defendants were aware, or should have been aware, that reasonable and prudent nurses at all hospital levels considered the physician's order to be the primary source for determining the appropriate drug concentration, not the concentration in the vial.

i. Defendants were aware, or should have been aware, that reasonable and prudent nurses at all hospital levels mistakenly considered so-called "smart pumps," such as the LifeCare PCA® Infusion System with Hospira MedNet™ Software, capable of delivering the drug concentration manually programmed into the pump, when in fact the drug concentration delivered to the patient was determined solely by the concentration of the drug in the vial inserted in the pump and could not be varied no matter what concentration was "programmed" into the pump.

j. Defendants were aware of the risk of misprogramming the drug concentration in that they designed a "fail safe" for such errors in which the drug concentration is entered automatically when the barcode reader reads the Abbott- or Hospira-manufactured vial barcode or a hospital pharmacy barcoded vial compatible with the bar code reader in the pump, thereby assuming a duty to protect the patient from inadvertent manual misprogramming of the drug concentration.

k. Defendants were further negligent in that the variety or "census" of drugs it offered for sale bearing its barcode, and therefore readable by its pump's barcode reader, was extremely limited.

l. Defendants were aware that numerous purchasers or lessees of its PCA pump did not have the capacity in their pharmacy to put Hospira PCA pump-readable barcodes on drugs intended for patient administration by such PCA pumps.

m. Defendants negligently chose to employ a proprietary barcode and barcode reader in its PCA pumps, and did so to encourage hospitals to purchase their PCA medications through Hospira in order to have the safety benefits of its drug concentration self-programming

n. Defendants negligently designed and manufactured a pump and its software with a self-programming "fail safe" in place, but which allowed nursing staff to unknowingly and unintentionally defeat the "fail safe" by manual programming.

o. Plaintiffs reserve the right to identify other or additional acts of negligence of Defendants during the course of discovery.

38. As a direct and proximate consequence of Defendants' aforesaid negligence, Decedent received a massive overdose of a narcotic drug which caused his death.

39. Plaintiffs, the statutory beneficiaries of the Estate of Joseph Seth Williamson, II, have been damaged as follows:

a. sorrow, mental anguish and loss of solace (including, but not limited to, the loss of Decedent's society, companionship, comfort, guidance, kindly offices and advice);

b. loss of the income of Decedent;

c. loss of the services, protection, care and assistance provided by Decedent; expenses for the care, treatment and hospitalization of Decedent incident to the injury resulting in death; and

d. such other damages as may seem fair and just to the jury.

WHEREFORE, Plaintiffs Deirdre Williamson Jain and Emily Ruth Williamson, Individually, and as Co-Administrators of the Estate of Joseph Seth Williamson, II, Deceased, pray for judgment in their favor and against Defendants in the amount of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages, together with the costs of this proceeding, prejudgment interest from October 7, 2011, post-judgment interest and any further relief that this Court may deem just and proper.

COUNT II
BREACH OF IMPLIED WARRANTIES OF MERCHANTIBILITY

40. Plaintiffs incorporate herein the allegations set forth in Paragraphs 1-39 as though set forth in full text.

41. As constituted by the regulatory process under which it was approved for marketing, sale, lease and use in the United States, the Hospira LifeCare PCA® Infusion System with Hospira MedNet™ Software consisted of the pump in question, its operating software and its System Operating Manual.

42. The subject product which was sold or leased by Defendants, directly or through intermediaries, to the hospital was unreasonably dangerous and for that reason, defective.

43. Decedent was a member of the class of patients for whom injury or death caused by the defect was foreseeable.

44. The product was unreasonably dangerous in the following ways:

a. It was marketed, promoted and sold or leased to hospitals as a next generation infusion pump which, by virtue of its onboard software, could prevent foreseeable programming errors and promote patient safety.

b. It was marketed, promoted and sold or leased to hospitals as a next generation infusion pump which, by virtue of its onboard software, could lockout or block specific programming errors; to wit, that by virtue of its engineering, the concentration of the drug to be delivered to the patient would automatically be read by its barcode reader and automatically programmed into the pump. In principal, not only would there be no need for the nursing staff to program the drug concentration, the pump could not be further programmed unless and until the bar code reader had read and recognized the bar code on the vial.

c. Contrary to such representations, the pump was unreasonably dangerous in that the automatic programming of the proper drug concentration was only true in two out of three circumstances. In the third instance, the nursing staff could manually program a mistaken concentration into the pump, and unlike the automatic lockout or blocking of an unrecognized barcode, the pump would accept any concentration the nursing staff chose to enter, and the pump would give no warning that the entered concentration was unreasonable, unsafe and dangerous.

d. The System Operating Manual for the pump was inadequate and defective in that it failed to give adequate instructions for use and adequate warnings for what foreseeable misprogramming errors might cause patient harm and how.

e. The System Operating Manual for the pump was inadequate and defective in that it encouraged the nursing staff to enter the drug concentration stated in the physician's prescription or order, not the drug concentration in the drug vial installed in the pump.

f. The digital display on the pump itself failed to give adequate instructions for use and warnings about the risk of misprogramming.

45. By selling or leasing the instant pump to hospitals in its unreasonably dangerous condition, Defendants breached their implied warranty of merchantability

46. As a direct and proximate consequence of Defendants' breach of its implied warranties of merchantability, Decedent received a massive overdose of a narcotic drug which caused his death.

47. Plaintiffs, the statutory beneficiaries of the Estate of Joseph Seth Williamson, II, have been damaged as follows:

a. sorrow, mental anguish and loss of solace (including, but not limited to, the loss of Decedent's society, companionship, comfort, guidance, kindly offices and advice);

b. loss of the income of Decedent;

c. loss of the services, protection, care and assistance provided by Decedent; expenses for the care, treatment and hospitalization of Decedent incident to the injury resulting in death; and

d. such other damages as may seem fair and just to the jury.

WHEREFORE, Plaintiffs Deirdre Williamson Jain and Emily Ruth Williamson, Individually, and as Co-Administrators of the Estate of Joseph Seth Williamson, II, Deceased, pray for judgment in their favor and against Defendants in the amount of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages, together with the costs of this proceeding, prejudgment interest from October 7, 2011, post-judgment interest and any further relief that this Court may deem just and proper.

COUNT III
BREACH OF EXPRESS WARRANTY

48. Plaintiffs incorporate herein the allegations set forth in Paragraphs 1-47 as though set forth in full text.

49. By expressly representing to the FDA, and to its customers that its PCA pumps had safety devices which would automatically program its PCA pumps with the drug identity and concentration in the vial placed in the pump, thereby sparing the patient the risk that the drug concentration might be misprogrammed, Defendants extended to all purchasers and lessees of its Hospira LifeCare PCA® Infusion System with Hospira MedNet™ Software an express warranty that the pump was reasonably safe for its intended uses.

50. Decedent was a third party beneficiary of that express warranty in that it was his safety, and the safety of other patients receiving PCA pump therapy, to whom those representations were intended to benefit.

51. Defendants breached their express warranties as described *supra.*

52. As a direct and proximate consequence of Defendants' breach of its express warranties, Decedent received a massive overdose of a narcotic drug which caused his death.

53. Plaintiffs, the statutory beneficiaries of the Estate of Joseph Seth Williamson, II, have been damaged as follows:

a. sorrow, mental anguish and loss of solace (including, but not limited to, the loss of Decedent's society, companionship, comfort, guidance, kindly offices and advice);

b. loss of the income of Decedent;

c. loss of the services, protection, care and assistance provided by Decedent; expenses for the care, treatment and hospitalization of Decedent incident to the injury resulting in death; and

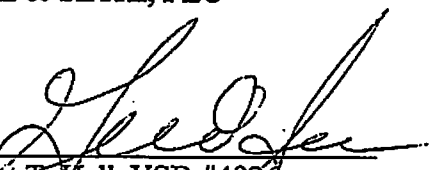
d. such other damages as may seem fair and just to the jury.

WHEREFORE, Plaintiffs Deirdre Williamson Jain and Emily Ruth Williamson, Individually, and as Co-Administrators of the Estate of Joseph Seth Williamson, II, Deceased, pray for judgment in their favor and against Defendants in the amount of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages, together with the costs of this proceeding, prejudgment interest from October 7, 2011, post-judgment interest and any further relief that this Court may deem just and proper.

A JURY TRIAL IS DEMANDED.

DEIRDRE WILLIAMSON JAIN, and
EMILY RUTH WILLIAMSON, Individually,
and as Co-Administrators of the Estate of
Joseph Seth Williamson, II, Deceased

HALL & SETHI, PLC



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Counsel for Plaintiffs

CERTIFICATE/LETTER OF QUALIFICATION Court File No. CWF11000236
COMMONWEALTH OF VIRGINIA
VA. CODE §§ 6.2-893, 6.2-1171, 6.2-1365, 6.2-1367, 37.2-1011, 64.1-122, 64.1-128

MONTGOMERY COUNTY Circuit Court

I, the duly qualified clerk/deputy clerk of this Court, CERTIFY that on October 13, 2011
DATE

DEIRDRE W JAIN AND EMILY RUTH WILLIAMSON,
NAME(S) OF PERSON(S) QUALIFYING

duly qualified in this court, under applicable provisions of law, as Administrator of the estate of

JOSEPH SETH WILLIAMSON II
☒ DECEASED ☐ MINOR ☐ INCAPACITATED

The powers of the fiduciary(ies) named above continue in full force and effect.

$42,000.00 bond has been posted.

Given under my hand and the seal of this Court on

October 13, 2011
DATE

ERICA W. WILLIAMS, Clerk

by _____, Deputy Clerk

FORM CC-1625 MASTER 10/10

PLAINTIFF'S EXHIBIT 1